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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,749

03/22/2005

In-San Kim

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07/13/2006

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EXAMINER

ARNOLD, ERNST V

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/528,749

Applicant(s)

KIM ET AL.

Examiner

Ernst V. Arnold

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/22/05</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

The Examiner acknowledges receipt of application number 10/528,749 filed on 03/22/2005 and is a 371 of PCT/KR02/01839 filed on 09/30/2002.

Claims 1-6 are pending in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "biopolymer" in claim 3 is used by the claim to mean "carboxymethylcellulose, hyaluronic acid, chitosan, polyacrylic acids, polyvinyl ethers, polystyrenes, cellulose ethers, cellulose esters, starches and polysaccharides", while the accepted meaning is "a macromolecule, such as a protein, formed in a living organism (Webster's II New College Dictionary page 111)." Clearly, polymers such as polystyrene are not made in a living organism. The term is indefinite because the

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specification does not clearly redefine the term. The Examiner suggests removing polymers not from a living organism.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al. (J. Craniofac. Surg. 2002 May 13(3), 465-75) in view of Liu (US 5,281,265).

Applicant claims a bone-filling composition for stimulating bone-formation and bone-consolidation comprising 1) 20 -80 weight% of mixture containing CaSO₄ (90-99 weight%) and CaCO₃, MgCO₃, CaCO₃ • MgCO₃ (1 – 10 weight%); and 2) 80-20 weight% of viscous biopolymer.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Cho et al. teach an injectable gel-type calcium sulfate mixed with carboxymethylcellulose in a syringe that is used for bone consolidation (Abstract; page 467, Figure 2). Cho et al. teach that the composition for bone consolidation is 50% calcium sulfate and 50% carboxymethylcellulose (Page 467, right column).

Liu teaches the resorbable calcium sulfate surgical cements for use in medical applications such as orthopedic and maxillofacial surgeries and dental applications comprising a biocompatible filler component selected from the group consisting of calcium carbonate, magnesium carbonate and mixtures thereof (Claims 1, 15 and 16). Liu teaches the weight ratio of the fillers to the cementing components can be up to 4 to 1 (Column 4, lines 41-53). Liu states that biocompatible filler component is substantially inert thus establishing that CaCO_3 , MgCO_3 , $\text{CaCO}_3 \cdot \text{MgCO}_3$ are secondary inert ingredients in the cement composition; thus they are optional and not required for the cement to function (Column 5, line 35 and claims 15 and 16).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Cho et al. do not expressly teach adding CaCO_3 , MgCO_3 , $\text{CaCO}_3 \cdot \text{MgCO}_3$ (1 – 10 weight%) to the composition.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add CaCO_3 , MgCO_3 , $\text{CaCO}_3 \cdot \text{MgCO}_3$, as suggested by Liu, to the composition of Cho et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Liu teaches that these fillers are inert with respect to the interaction between the cementing component and the setting component. The adjustment of particular working conditions (e.g., determining an appropriate amount of CaCO_3 , MgCO_3 , $\text{CaCO}_3 \cdot \text{MgCO}_3$ to add to the composition) is deemed merely a matter of routine optimization

It is the Examiner's position that In the absence of any criticality/unexpected results, the presently claimed invention is considered prima facie obvious over the prior art for the reasons of record and those stated above.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

A prior art disclosure is not limited to its working examples or to its preferred embodiments. (*Merck & Co. Inc. v. Biocraft Labs. Inc.*, 874 F.2d 804, 807, 10 USPQ2d 1843, 1846 (Fed. Cir. 1989); *In re Fracalossi* 681 F.2d 792, 794 n. 1, 215 USPQ 569, 570 n.1 (CCPA 1982); *In re Lamberti*, 545 F.2d 747, 750, 192 USPQ 278, 280 (CCPA 1976); *In re Boe*, 355 F.2d 961, 965, 148 USPQ 507, 510 (CCPA 1996).

Accordingly, the burden of proof is upon Applicants to show that the instantly claimed subject matter is different and unobvious over those taught by the prior art. (See: *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

No claims are allowed.

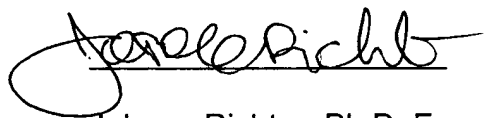
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
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A handwritten signature in black ink, appearing to read 'Johann Richter', with a large, stylized loop at the beginning.

Johann Richter, Ph.D. Esq.
Supervisory Patent Examiner
Technology Center 1600